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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,029	07/24/2001	Gabor Bogye	21965	6045

535 7590 01/27/2005

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,029	BOGYE, GABOR	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13,15,16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13,15,16 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed September 24, 2004 have been entered.

The cancellation of claims 14, 17-18 is acknowledged. The addition of claims 19-25 is acknowledged.

Claims 9-13, 15-16, and 19-25 are pending.

The outstanding rejections under 35 USC 101 and 35 USC 112, second paragraph are withdrawn in view of the amendments filed September 24, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 13-15, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for folic acid, Vitamin B6, Vitamin B12, betaine, choline, acetylcysteine, does not reasonably provide enablement for other plasma homocysteine content reducing agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue

experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define "plasma homocysteine content reducing agents". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "plasma homocysteine content reducing agents" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. They do not belong to a single chemical class, nor they have a similar chemical structure or physical properties. In essence, applicant merely defines the compounds needed using functional language. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true,

but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention. The instant specification is so lack of guidance, one of skilled in the art would be required to assess each embodiment individually for physiological activity. The instant claims read on all plasma homocysteine content reducing agent(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Response to arguments

Applicant's arguments filed September 24, 2004 averring the term "plasma homocysteine content reducing agents" as well-known in the art have been considered, but are not found persuasive. Applicant specifically argues, by citing several journal articles, that one of skilled in the art will be able to determine if any particular compound is an effective agent to reduce plasma homocysteine levels in patients without undue experimentation [emphasis added]. Applicant's arguments are directed to how to screen a compound. The problem of applicant's arguments is that the instant specification does not provide sufficient information to determine what compounds would be likely useful. Examiner notes that the "plasma homocysteine content reducing agents" examples listed in the instant specification contains vastly different structures. There is no information as to the structure-activity relationship of the "plasma homocysteine content reducing agents" disclosed in the instant specification. In other words, what structural characteristics, functional groups or moieties make a compound useful as "plasma homocysteine content reducing agent"? Examiner admits that if a particular compound identified or synthesized, then it may not be unduely burden to one of skilled in the art to determine whether that particular compound as useful in the instant invention; however, the instant specification does not even provide sufficient information to one of skilled in the art what compounds are encompassed by such expression. Therefore, any and every compounds known to man would be potential candidates for practicing the instant invention. One of skilled in the art would then have to perform undue experimentation to ascertain appropriate compounds in order to practice the full scope of the invention. The articles cited in the arguments merely

provide the screening methods or assays for determining if particular compounds as effective as "plasma homocysteine content reducing agents". But what if there is no compound to start screening with? These articles are not directly address to issue set forth in the rejection under 35 USC 112, first paragraph: applicant are using functional language at point of novelty.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13, 15-16, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Ali et al. (Preventive Medicine, 1995;24(5):528-534) as evidenced by USDA Nutrient Database, Release 12, 1998, Monograph No. 01077).

Ali et al. teaches elderly women taking HRT (Hormone Replacement Therapy) and at the same time drinking milk (See the abstract).

Since milk containing vitamin B6, B12, and folic acid (See USDA Nutrient Database 01077), the method of women taking both HRT and milk taught in Ali would read on the herein claimed method (See *Ex parte Novitski*,26 USPQ2d 1389 (BOPA 1993), *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989), and *In re Winkhaus*, 52 F.2d 637, 188 USPA 219 (CCPA 1975) and explanation below).

Claims 19, 20, 23, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Spellacy et al. (Contraception, 1972;6(4):263-273).

Spellacy et al. teaches vitamin B6 supplement is administered to women taking progesterone containing oral contraceptive (See the abstract).

Claims 19, 20, 23, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterworth et al. (Am. J. Clin. Nutr., 1982;35(1):73-82 from IDS received 1/2/2002).

Butterworth et al. teaches folic acid was supplemented to women taking progesterone containing oral contraceptive (See the abstract).

Examiner notes that the method steps taught in the prior art are the same as herein claimed. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a treatment utility anticipates claims directed to such treatment. Arguments that such treatment is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*,

supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated treatment utility, renders such claims anticipated by the prior inherent use.

Response to Arguments

Applicant's arguments filed September 24, 2004 with regard to the specific patient populations with elevated homocysteine level being caused by gestagen administration have been considered, but are not found persuasive. The homocysteine-elevating activity of progesterone is considered as inherently present in patients taking progesterone. Therefore, although the cited prior arts are silent with regard to the patient's homocysteine level, the patients are considered having elevated homocystein level since they are taking progesterone.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617